REMARKS

Claims 4, 5, 32, 44-47 and 56-59 were rejected under 35 U.S.C. §112, first paragraph. Claims 4 and 5 have been amended to recite that the amount of lysostaphin analogue(s) administered is from 0.5 to 30 mg/kg/day. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

The cancellation of withdrawn Claims 28 and 35 was requested (see pg. 2 of the Official Action). These claims will be canceled upon the indication of allowable subject matter.

Claims 4, 5, 32, 41-51 and 56-60 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zygmunt and Goldberg and Stark and further in view of Oldham. Claims 32, 42, 43, 46, 47, 50, 51, 54 and 55 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zygmunt and Goldberg and Stark and Oldham and further in view of Dixon. These rejections, which appear on pages 3-5, paragraphs 4 and 5 of the Official Action, are respectfully traversed for the following reasons.

With regard to the Zygmunt reference, the Official Action states that the reference describes intravenous administration of lysostaphin in doses within the instantly claimed range (see page 3 of the Official Action). However, the Official Action has pointed to no teaching in Zygmunt of a method as claimed comprising the administration of multiple doses of the lysostaphin analogue in an amount of from 0.5 to 30 mg/kg/day.

With respect to Goldberg, the Official Action states that the reference describes the treatment of dogs (i.e., dogs 4-7) having staphylococcal endocarditis with multiple doses of lysostaphin within the instantly claimed ranges. As set forth below, however, Dogs 4, 5 and 6 were in fact administered dosages outside of the claimed range. The Official Action inquires into the method of calculating the amount of lysostaphin administered in mg/kg/day. The dosage in mg/kg/day was calculated from the data in Goldberg as follows:

$$dosage(mg/kg/day) = \frac{(MeanDose) \times (No.Doses)}{(No.DaysTreated)}$$

Using the above formula, it can be clearly seen that Dogs Nos. 4, 5 and 6 were in fact administered dosages outside of the claimed range. In particular, Dog No. 4 received a dose of 35.4 mg/kg/day, Dog No. 5 received a dose of 31.6 mg/kg/day and Dog No. 6 received a dose of 57 mg/kg/day. This information is included in the tables submitted in the response filed March 20, 2003 (Paper No. 28). As set forth in that response, of all the Dogs evaluated in Goldberg, only Dogs. 7 and 10 received a dosage within the claimed range. As further set forth in this response, both of those dogs were indicated to have "relapsed". In view of the above, it is respectfully submitted that the cited references fail to teach or reasonably suggest the claimed invention. In particular, it is respectfully submitted that it would not have been obvious in view of Goldberg to administer dosages within the claimed range to humans when these same dosages resulted in relapse in dogs. As set forth in the Official Action, Goldberg discloses that the treatment of dogs with staphylococcal endocarditis "simulates" the treatment of established staphylococcal infection in man (see page 4 of the Official Action). Moreover, one of ordinary skill in the art would not have been motivated to employ treatment regimens in humans which resulted in relapse in a dog model, particularly when, as acknowledged in the Official Action, the dog model is known to simulate treatment in humans. Accordingly, it is respectfully submitted that the references cited in the Official Action fail to teach or reasonably suggest the claimed invention. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

On page 4 of the Official Action, it was asserted that the claims do not exclude the use of another antibiotic and that "synergism of lysostaphin with other antibiotics is well known . . .

which motivates an artisan to reduce dosage of lysostaphin". However, no references were cited in support of this assertion. Further, it is not clear if the claims are being rejected over these other references since the Official Action asserts that " . . . the issue that was not addressed yet, but will be brought up if necessary . . ." (Pg. 4 of the Official Action). Clarification is respectfully requested. Further, applicants hereby request that references be provided in support of the above assertion.

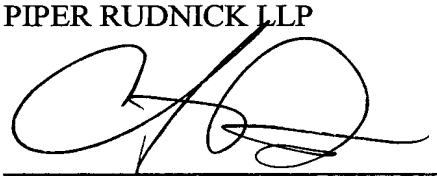
Additional claims 61-66 have been added to further clarify the applicant's invention. Support for these claims can be found in the specification at least at pg. 8 and pp. 20-21.

CONCLUSION

All rejections having been addressed by the present amendments and response, Applicants believe that the present case is in condition for allowance and respectfully request early notice to that effect. If any issues remain to be addressed in this matter which might be resolved by discussion, however, the Examiner is respectfully requested to call Applicants' undersigned counsel at the number indicated below.

Respectfully submitted,

PIPER RUDNICK LLP



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